CORN REFINERS ASSOCIATION

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April 1, 2003

Robert Lake
Director, Office of Regulations and Policy
Center for Food Safety and Applied Nutrition
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0276 (Registration of Food Facilities)

Dear Mr. Lake:

The Corn Refiners Association, Inc. (CRA) appreciates the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA) proposed rule to implement the food facility registration provision of the Public Health Security and Bioterrorism Preparedness Act of 2002 (the Bioterrorism Act).

The Corn Refiners Association, Inc. is the national trade association representing the corn refining (wet milling) industry of the United States. Members of the Association produce food and industrial starches, sweeteners, ethanol, feed ingredients, vegetable oil, organic acids, amino acids and polyols using the corn wet milling process. The Association, and its predecessors, has served this important segment of American agribusiness since 1913. A list of our members is attached to these comments.

CRA strongly supports strengthening the safety and security of the U.S. food supply, and has worked diligently with its member companies to provide helpful and accurate food safety information to the public. We commend FDA for swiftly fulfilling its obligations under the Bioterrorism Act to avoid the undesirable statutory defaults included therein.

We would, however, like to express our concerns with the proposed food facility registration rule. At the meeting held on January 29, 2003, FDA stated that a food facility is only responsible for registering its own facility. In order to ensure timely receipt of imports from foreign vendors, it is imperative that our member organizations dedicate significant resources to familiarize them with the proposed rules to avoid costly delays of shipments that have the potential to ripple through all sectors of U.S. food production. With the global nature of today's economy, any slow down along a facility's supply chain can have extreme repercussions. Not only does this provide a financial burden, but it provides a level of responsibility for importers that is not in keeping with the spirit of the Bioterrorism Act. We encourage FDA to facilitate education regarding the new rule to provide foreign facilities with information necessary to maintain the flow of trade in the United States.

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significant administrative expenses for both the importer and FDA, without a clear benefit of added security to the food supply.

We ask FDA to amend the proposal as follows: Bulk commodities, as identified by the appropriate FDA number, would be granted a 10% variance on quantity reporting requirements. We believe this will provide an equitable balance between the need for FDA to control the risk associated with changes in quantity without adding undue administrative expense to the importer or FDA.

Secondly, we are concerned that FDA has underestimated the amount of trade along our borders with Canada and Mexico by rail conveyance. Few companies own dedicated railways to transport their goods between domestic and other North American facilities. Generally, a rail transporter is contracted to ship product between these locations, and most often is contracted by other companies at the same time. The failure on the part of one company to provide adequate prior notice has the potential to severely delay the product of several other companies. We contend that the information most likely to delay such a conveyance will be the inaccuracy of the time of arrival and the port of entry, information that is beyond the importers' control, and best answered by the transporter.

Therefore, we request that FDA allow transporters to file amendments to otherwise complete prior notices forms, of time of arrival and port of entry, as contractually agreed upon between the importer and transporter. This will serve to reduce the number of incorrect prior notices and prevent extremely costly delays along our borders, without loss of security along the food chain.

Another issue of concern of special applicability to those companies that have manufacturing facilities close to the Canadian or Mexican borders is that of lot numbers. For bulk ingredients, the lot number is created at the time of loading. Delivery of the loaded vehicle from these facilities to the United States could take place within two hours. Under the proposed rule, companies with such facilities would be forced to pre-load U.S. shipments at significant additional expense. We request that FDA allow the amendment period for lot number assignments to be extended until just prior to reaching the U.S. border.

Additionally, we believe the information requested in the proposed rule is duplicative to that of many items U.S. Customs already requires. We are aware that FDA is under a regulatory deadline, but we strongly recommend that FDA and U.S. Customs continue their collaboration to reduce the burden of paperwork to importers, as well as to FDA and Customs. We support ongoing efforts by FDA and Customs that will provide a synchronized reporting system for imports regulated by FDA and Customs.

Further, we suggest that FDA review the U.S Customs joint voluntary security initiative by government and business called C-TPAT (Customs Trade Partnership Against Terrorism). The goal of C-TPAT is to build cooperative relationships that strengthen the overall supply chain, including border security. Participants in this program are required to:

A. Conduct a thorough self-assessment of supply chain security;
B. Develop and implement a program designed to enhance security throughout the supply chain; and
C. Encourage other companies in the supply chain to participate and undertake similar security enhancements.

Participants in the program have significantly reduced the risks of bio-terrorist activity associated with food importation. C-TPAT participants proactively address FDA's underlying concern of adequate time for risk assessment for each importation. While FDA's need to inspect imports remains a critical component of its obligations under the Bioterrorism Act, we believe the 12-hour prior notice requirement represents a redundant and unnecessary step for those companies participating in the C-TPAT program.

We respectfully ask FDA to amend the proposal to exempt C-TPAT companies from the "12-hour" requirement of prior notice. In doing so, the administrative expense for both the importer and FDA will be minimized with no appreciable loss in food chain security. In addition, the FDA will be better able to focus its resources on imports that pose a greater risk.

Alternately, we would like to suggest that FDA provide three options for filing prior notice.

- Option one: An importer is given until noon of the calendar day prior to the shipment's arrival in the U.S. to provide prior notice, with the ability to provide amendments and updates, as proposed.

- Option two: Allows an importer to file four hours prior to the arrival of the shipment, but disallows amendments and updates of any kind. As the use of amendments and updates must be done within two hours of a shipment's arrival, we believe that FDA has adequate time to make inspection decisions for a complete prior notice filed four hours in advance. This flexibility reduces the number of amendments and updates to be filed, and does not detract from FDA's ability to make inspection decisions.

- Option three: Allows an importer to file four hours prior to the arrival of the shipment with the ability to amend only the quantity and lot number up to the arrival at the port of entry. This option facilitates the smooth flow of trade for those U.S. companies that have manufacturing facilities within minutes of the U.S./Canadian or Mexican borders.

We believe that the modifications outlined above to FDA's proposed rule on Prior Notice of Imported Foods are consistent with U.S. obligations under the World Trade

Organization Sanitary and Phytosanitary Measures Agreement to "ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection". We thank you for the opportunity to provide FDA comments on the proposed rule for prior notice of imported foods provision of the Bioterrorism Act.

Sincerely,

Audrae Erickson
President

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